Report on Provisionally Notifiable Conditions

March 4, 2004

Executive Summary

WAC 246-101-015[1] established a number of conditions as being "provisionally notifiable" as of December 2000. The stated goal of this rule was to "collect enough information to determine whether requiring notification improves public health," i.e., to collect enough information to determine whether these conditions should be made *permanently* notifiable or whether they should not be notifiable at all. In accordance with this goal, the rule required that the department write an assessment report—this report—and that the Board use that report to decide the fate of the provisionally notifiable conditions by April 2004.

The department's recommendations are summarized in the table below. Later in this report are details regarding those conditions that the department is recommending to make permanently notifiable. Not contained in this report (but available upon request) are details regarding invasive group A streptococcal infections, which the department is recommending to delete from the notifiable conditions system. The basis for this recommendation is that there is no clear intervention to prevent transmission of group A streptoccocus in most situations. [2]

Department of Health recommendations

Make the following conditions permanently notifiable	Delete the following from the notifiable conditions system
Autism **Cerebral palsy** **Abdominal wall defects** **Fetal alcohol syndrome/fetal alcohol effects** **Hepatitis C** **Chronic hepatitis B**	**Invasive group A streptococcus**

[1] http://www.leg.wa.gov/wac/index.cfm?fuseaction=Section&Section=246-101-015

[2] An exception is healthcare-related infections, but these already are (and will continue to be) notifiable to public health as nosocomial infections.

In accordance with the stipulations of the rule, this report evaluates the provisionally notifiable conditions by examining the questions listed below. (General conclusions are also provided where possible. For details, see the specific answers for each condition in the full report.)

A. Estimate the societal cost resulting from the provisionally notifiable condition by (**A1**) determining the prevalence of the provisional notifiable condition; (**A2**) identifying the quantifiable costs resulting from the provisionally notifiable condition; and (**A3**) discussing the qualitative costs resulting from the provisionally notifiable condition.

General conclusion: The societal costs for each of these conditions is large. Estimates of quantifiable costs range from $4 million per year (for the annual costs of treating herpes in Washington State) to over $100 million (for the lifetime costs resulting from the number of cases of autism or cerebral palsy that occur in Washington State each year). Qualitative costs are also significant.

B. Describe how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition.

General conclusion: The information provided by the provisional notification requirement has (or, in some cases, will) be used to improve public health. For example, the department has used the data to improve herpes prevention initiatives, will be able to follow-up to ensure proper care for children with birth defects, and will be able to engage in proactive herpes vaccination efforts if the vaccine currently under development is proves to be safe and effective.

C. Describe the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition.

General conclusion: Previous intervention strategies, when they existed, were of mixed effectiveness. For example, some but not all birth defects were voluntarily reported to DOH prior to provisional notification; this prevented appropriate follow-up for all affected children. In the case of STD prevention efforts, previous intervention efforts were based on available information (e.g., nationwide data) rather than information specific to Washington State. Also, some opportunities (e.g., the $600,000 herpes grant that UW/Harborview received from the CDC) are unlikely to have been available in the absence of notification requirements.

D. Identify the quantitative and qualitative costs of the provisional notification requirement.

General conclusion: The major cost of the provisionally notifiable conditions requirements is the time required for providers to create reports and for DOH staff to process the reports. Estimates of the resulting costs are small, with a maximum of $10,000 per year for herpes reporting.

E. Compare the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement.

General conclusion: Comparing the costs and benefits of the provisional notification requirement is difficult; however, it seems likely that the benefits outweigh the costs for all conditions (except invasive group A streptococcus).

F. Describe the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data.

General conclusion: The notifiable conditions process is the best available process. In some cases (e.g., abdominal wall defects), it is an excellent mechanism for collecting the relevant data; in other cases (e.g., herpes), it has serious weaknesses but is superior to any of the viable alternatives.

G. Determine whether or not a less burdensome data collection system would provide the information needed to effectively establish and maintain the intervention strategies.

General conclusion: Other data collection systems would not provide the relevant information, e.g., because no such systems exist, or (as with CHARS reporting of birth defects) because other systems fail to identify patients by name or in a timely manner.

Birth defects (autism, cerebral palsy, abdominal wall defects, and fetal alcohol syndrome/fetal alcohol effects)

This section covers four provisionally notifiable birth defects: autism, cerebral palsy, abdominal wall defects, and fetal alcohol syndrome/fetal alcohol effects (FAS/FAE). Where necessary, as in the introductory paragraphs below, subsections provide information specific to each condition.

Autism

Autism spectrum disorders (ASDs) cover a wide range of behaviors and abilities. ASDs include autistic disorder, pervasive developmental disorder - not otherwise specified (PDD-NOS, including atypical autism), and Asperger disorder. These three conditions all have some of the same symptoms, but they differ in terms of when the symptoms start, how fast they appear, how severe they are, and their exact nature. These three conditions, along with Rett syndrome and childhood disintegrative disorder, make up the broad diagnosis category of pervasive developmental disorders.

Although the cause of autism is not known, it is believed that both genetic and environmental factors might play a role.

Cerebral palsy

Cerebral palsy refers to a group of disorders that affect a person's ability to move and to maintain balance and posture. It is due to a brain abnormality that is nonprogressive, meaning that it does not get worse over time. The exact symptoms, however, can change over a person's lifetime.

There are considered to be many possible causes of cerebral palsy, including infections during pregnancy, Rh disease, premature separation of the placenta, brain injury as a young child, and other birth defects. As the medical management of pregnancy and delivery have become more refined, many of these causes have become less prominent. Today, most cases of cerebral palsy occur with no identifiable risk factors.

Abdominal wall defects

Abdominal wall defects mainly include gastroschisis and omphalocele. In gastroschisis, thought to be caused by an obstruction of an umbilical vein, the intestines protrude outside of the abdomen without a membrane covering the contents. Gastroschisis is repaired within hours of the birth. In omphalocele, the bowel protrudes into the umbilicus and is always covered by a membrane. The condition is often associated with

chromosomal abnormalities and multi-defect syndromes. Omphalocele is also initially repaired surgically; however, there is not the same urgency as with gastroschisis.

With both conditions follow-up surgery is often required a few months later. Both conditions can provide complications throughout childhood requiring follow-up

The causes of gastroschisis and omphalocele, although not understood, are thought to differ between the two conditions. There are no known strategies to reduce these defects. Prevention is limited to reducing the long-term consequences of these conditions.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

Prenatal exposure to alcohol can cause a spectrum of disorders. One of the most severe effects of drinking during pregnancy is fetal alcohol syndrome (FAS). Many terms have been used to describe children who have some, but not all, of the clinical signs of FAS. Three terms are fetal alcohol effects (FAE), alcohol-related neurodevelopment disorder (ARND), and alcohol-related birth defects (ARBD). FAE has been used to describe children who have all of the diagnostic features of FAS, but at mild or less severe levels. In 1996, the Institute of Medicine (IOM) replaced FAE with the terms ARND and ARBD.

A. Estimate the societal cost resulting from the provisionally notifiable condition [by answering the following:]

A1. Determine the prevalence of the provisional notifiable condition.

Autism

NIH and CDC estimates suggest a prevalence ranging from 10 to 67 cases per 10,000 live births. Washington State averages 80,000 live births per year, meaning approximately 80 to 296 cases per year.

Cerebral palsy

The prevalence of cerebral palsy is thought to range between 20 and 30 cases per 10,000 children, or between 160 and 240 cases per year in Washington State.

Abdominal wall defects

The reported rate in Washington State during 2000-2002 was about 72 cases per year, i.e., about 9 cases per 10,000 births. This incidence is higher than the 3-5 cases per 10,000 births reported in the literature.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

Prevalence estimates for FAS vary widely depending on the population studied and the surveillance methods used. CDC and NIH studies show FAS rates ranging from 2 to 20 (or even higher in high-risk populations) per 10,000 live births. Other prenatal alcohol-related conditions, such as alcohol-related neurodevelopment disorder (ARND) and alcohol-related birth defects (ARBD) are believed to occur approximately three times as often as FAS. NIH estimate that the prevalence for FAS, ARBD, and ARND combined is 1 percent of all births. Washington State averages 80,000 live births per year, meaning approximately 40-160 cases of FAS and another 400 cases of ARBD/ARNP. Based on NIH's combined estimate of 1% of FAS/ARBD/ARNP, there could be as many as 800 cases per year.

A2. Identify the quantifiable costs resulting from the provisionally notifiable condition.

Autism

A recent journal article[3] estimated the median weekly cost of autism in Britain at £650 per case. (It is important to note that this included estimated parental costs in terms of time, lost income, etc.) At an exchange rate of £0.57 per $1.00, a comparable estimate would be $1,140 per week. Using a discount rate of 5%, this extrapolates to a discounted present value of lifetime costs of approximately $1.1 million per case.

Another perspective on costs comes from the California Dept of Developmental Services, which identified that individuals on DDS caseload with autism had almost twice the cost per client than those on their caseload without autism.

Cerebral palsy

Quantifiable cost estimates per case range from $350,000 (from the EPA's Cost of Illness Handbook, using a 5% discount rate) to $1,000,000 (from the CDC).[4] With 160-240 cases per year in Washington State, an estimate of total lifetime costs arising from each year's cases is $56-$240 million.

[3] Järbrink, Krister et al., "Measuring the Parental, Service and Cost Impacts of Children with Autism Spectrum Disorder: A Pilot Study," *Journal of Autism and Developmental Disorders*, 33(4): 395-402 (2003).

[4] The EPA and CDC websites are <http://www.epa.gov/oppt/coi/docs/III_7.pdf> and <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5303a4.htm>, respectively.

Abdominal wall defects

Waitzman (1992) estimates the cost of Gastrocschisis to be $108,000 per case and the cost of Omphalocele to be $176,000 per case. With 72 cases per year in Washington State, an estimate of total costs arising from each year's cases is $8-$13 million.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

The National Institute of Health[5] estimated nationwide economic costs of about $2 billion in 1992 as a result of FAS. Assuming that Washington State—which accounts for about 2% of the U.S. population—has the same proportion of cases as the United States as a whole, we can estimate statewide costs of about $40 million per year. This figure matches DOH estimates.

Another perspective comes from a study in North Dakota, which estimated that the medical costs of children with FAS were $2,342 per year more than children without FAS. The 10-year savings from avoiding FAS were $128,810; the 20-year savings were $ 491,820.

A3. Discuss the qualitative costs resulting from the provisionally notifiable condition.

In addition to medical costs and other issues discussed below, costs for a special needs child also include all of the direct support costs such as transportation, educational services, and special housing requirements. Additionally, there are significant indirect costs due to the emotional and psychological impacts on parents and siblings of children with special needs. They experience higher rates of absenteeism from work, illness, counseling and other supportive services.

Autism

There is currently no cure for autism, but appropriate treatment may foster relatively normal development and reduce undesirable behaviors. Educational/behavioral therapies and drug interventions are designed to remedy specific symptoms. Educational/ behavioral therapies emphasize highly structured and often intensive skill-oriented training. Doctors also may prescribe a variety of drugs to reduce symptoms of autism. Other interventions are available, but few if any scientific studies support their use.

People with autism have normal life expectancies. Symptoms in many children improve with intervention or as the children age. Some people with autism eventually lead normal or near-normal lives. Adolescence can worsen behavior problems in some children, and

[5] The NIH report, "The Economic Costs of Alcohol and Drug Abuse in the United States – 1992", can be found at <http://www.nida.nih.gov/EconomicCosts/Chapter4b.html#4.4>.

parents should be ready to adjust treatment for the child's changing needs. About a third of children with autistic spectrum disorders eventually develop epilepsy. The risk is highest in children with severe cognitive impairment and motor deficits.

Cerebral palsy

The symptoms of cerebral palsy vary from person to person. Symptoms can also change over time. A person with severe cerebral palsy might not be able to walk and might need lifelong care. A person with mild cerebral palsy, on the other hand, might walk a little awkwardly, but might not need any special help. People with cerebral palsy can have other disabilities as well, e.g., seizure disorders, vision impairment, hearing loss, and mental retardation.

Abdominal wall defects

Although surgical repair can be performed early, a high percentage (42%) of post-surgical complications occur. Children should be followed closely for normal intestinal functioning and normal weight gain. Children with omphalocele have a varied need for follow-up depending on other defects found.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

Children with alcohol related disorders suffer from a variety of medical and developmental problems, which may include any of the following:

- small for gestational age or small in stature in relation to peers;
- facial abnormalities such as small eye openings;
- poor coordination;
- hyperactive behavior;
- learning disabilities;
- developmental disabilities (e.g., speech and language delays);
- mental retardation or low IQ;
- problems with daily living;
- poor reasoning and judgment skills;
- sleep and sucking disturbances in infancy.

Children with FAS are at risk for psychiatric problems, criminal behavior, unemployment, and incomplete education.

B. Describe how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition.

The notifiable conditions requirement is part of an "enhanced passive" surveillance system that DOH is developing in conjunction with a web-based birth defects registry. This registry has been used to report abdominal wall defects (and eight other notifiable conditions) since 2000; DOH is currently working on expanding the registry to include autism, cerebral palsy, and FAS/FAE. When completed, the registry will be a great improvement over the previous system (described in part C below) in terms of identifying children and ensuring that they receive appropriate treatment.

The goals of the birth defects surveillance system are to identify trends, evaluate prevention efforts and to identify children at the earliest possible ages and refer them into the Children with Special Health Care Needs Program (CSHCN) for follow-up, treatment and supportive services. Local CSHCN coordinators facilitate access to all services at the community level including primary and tertiary medical care, psycho-social services, occupational, physical and speech therapies and other early intervention services.

Contracts are in place to develop and publish materials for each of the notifiable conditions. Materials are being made available to county CSHCN coordinators to disseminate to local providers and parents. A special emphasis is being made to ensure that materials are made available in the rural parts of the State.

Autism

Early and intensive education can help children grow and learn new skills. The goal of these efforts is to help with the difficult symptoms of an ASD in a child and to improve the child's skills that help him or her talk, interact, play, learn, and care for his or her needs. Prognosis is greatly improved if a child is placed into an intense, highly structured educational program by age two or three. Autistic children perform stereotypic behaviors such as rocking or twiddling a penny because engaging in repetitive behaviors shuts off sounds and sights, which cause confusion and/or pain. The problem is that if the child is allowed to shut out the world, his brain will not develop. Autistic and PDD children need many hours of structured education to keep their brain engaged with the world.

Medicines can relieve symptoms and be helpful for some people, but structured teaching of skills (often called behavioral intervention) is currently the most effective treatment.

Cerebral palsy

Since there is no cure, treatment of cerebral palsy is currently limited to improving the quality of life and functioning of the individual. Medically, a patient can have surgery to

improve balance or reduce spasticity or be provided appliances such as wheelchairs and walkers. In some cases medications may help the patient.

Since the needs of the child are varied and great, a team is generally needed that includes pediatricians, surgeons, occupational and physical therapists, speech therapists, social workers, etc.

Abdominal wall defects

Since gastroschisis is not usually associated with other defects, treatment is limited to the surgeries needed to repair the defect and follow up through childhood for abnormal intestinal functioning. Children with omphalocele have a wider involvement of other organs and, consequently, the range of needs that need follow-up is much higher. Long term behavioral consequences are also associated with omphalocele.

Fetal alcohol syndrome/fetal alcohol effects

Early identification is crucial so that families can be referred into treatment programs. The birth defects registry and CSHCN program provides a vital link is the process of early identification and referral.

Reducing incidence: FAS/ARBD/ARNP can be prevented if a woman abstains from drinking during pregnancy. A variety of programs have been developed to prevent drinking during pregnancy and the resulting health problems. These programs are described by NIH as universal (targeting all people in the population), selective (targeting women of reproductive age) and indicated (targeting mothers of FAS babies or known alcohol abusers). There is currently little research available on the efficacy of these different programs.

Reducing morbidity: Early intervention is a critical element in determining the prognosis for a child with FAS/FAE. The earlier in the child's life that medical, clinical and educational interventions can be provided, the better the outcome. Stable, structured, nurturing environments are necessary to support the child's growth and development. Special needs pre-school programs that are center-based and enroll parent and child can provide the most enriched experience. During the early years, the focus of treatment should be on establishing healthy parent/child relationships, motor and language development and sensory processing development.

C. Describe the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition.

Between 1987 and 1991, DOH had an active surveillance program that worked proactively to identify children with birth defects and notify county health officers, who would follow up to ensure that the children were receiving appropriate treatment. This active surveillance program did not receive funding after 1991, and it was replaced with a passive surveillance program that relied on providers to voluntarily notify DOH regarding children with birth defects. The effectiveness of this program has been spotty, especially when considering the importance of early intervention for the treatment of many birth defects. The "enhanced passive" surveillance system described above will be a significant improvement.

D. Identify the quantitative and qualitative costs of the provisional notification requirement.

At DOH, the Birth Defects Registry is staffed with a part-time ITAS (Information Technology Assistant Specialist and part-time HSC (Health Services Consultant) employees. The registry database is managed using MS Access. A web-based application using Transact Washington is in final testing. Education and promotion of the registry is accomplished by staff from the Genetic Services and CSHCN programs. As staff from these sections meet with the different providers around the state, reporting requirements and use of the registry is included in the discussions.

Hospitals currently report cases using one of two methods. Larger hospitals generate lists of patients, demographic characteristics, diagnoses and dates from administrative systems. These lists are sent to DOH in either hardcopy form or as ASCII files. Smaller hospitals can either generate list electronically or complete the forms manually.

When the web-based system is functional, hospitals will be able to either continue the methods they have used or upload data directly into the registry and run reports for their facility. Non-hospital providers will be given the same reporting options as hospitals.

Once the web-based registry is operational, costs to DOH will be minimal: the department will simply collect reports and pass information along to county coordinators. Costs to providers of reporting notifiable conditions will be more significant. Assuming that it takes 5 minutes to file each report, that providers' labor costs for clerical and clinic staff are approximately $40 per hour, and that there are 1,200 cases per year, annual costs to providers will be about $4,000 per year.

E. Compare the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement.

A quantitative comparison is difficult, but the cost savings that result from early intervention are likely to be significantly greater than the costs of the provisional notification requirement.

F. Describe the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data.

Autism

The birth defects surveillance program has relied on hospital inpatient data for the nine structural conditions currently reported. However, this will not identify the majority of autism cases. To do so, the surveillance team will work with Geraldine Dawson PhD, who runs a nationally recognized autism clinic at the University of Washington, and with other developmental pediatricians and the Autism Outreach Project working within the public school system.

Cerebral palsy

The birth defects surveillance program has relied on hospital inpatient data for the nine structural conditions currently reported. However, this will not identify the majority of cerebral palsy cases. To do so, the surveillance will work with the regional genetic clinics around the state. The Genetic Services program already has contractual relationships with these entities that include reporting. It is anticipated that reporting of these cases will not add an additional burden.

Abdominal wall defects

Since abdominal wall defects are identified at delivery, passive reporting by hospitals is expected to be high.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

FAS/FAE is under-identified and under-reported. As such, multiple sources must be utilized to identify cases. Making it a notifiable condition allows us to aggregate cases from multiple sources. More importantly, children with early referral into treatment and follow-up fare much better than children with late or no referral into treatment and follow-up.

G. Determine whether or not a less burdensome data collection system (example: biennial surveys) would provide the information needed to effectively establish and maintain the intervention strategies.

DOH already maintains a web-based birth defects registry for several other conditions. That system includes a referral process to the Children with Special Health Care Needs (CSHCN) program.

Autism

There is no other mechanism that can fulfill both goals of the program, good case identification from multiple sources and early referral into treatment and follow-up.

Cerebral palsy

There is no other mechanism that can fulfill both goals of the program, good case identification from multiple sources and early referral into treatment and follow-up.

Abdominal wall defects

The notification requirement is the least obtrusive and costly mechanism available to identify these cases from multiple sources. Hospitals are already identifying and reporting several other birth defect conditions. Most of the cases are identified through a routine review of computerized administrative records. This adds an incremental cost onto the existing system.

Fetal Alcohol Syndrome/Fetal Alcohol Effects

There is no other mechanism that can fulfill both goals of the program, good case identification from multiple sources and early referral into treatment and follow-up.

Hepatitis B, chronic – Initial diagnosis and previously unreported prevalent cases

According to the CDC[6], Hepatitis B is a serious disease caused by a virus that attacks the liver. The hepatitis B virus (HBV) can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death.

Hepatitis B is spread by direct contact with the blood or body fluids of an infected person; babies can also get hepatitis B from infected mothers during childbirth. The disease is not spread by food or water or through casual contact.

A vaccine has been available since 1981. The vaccine prevents infection and is routinely recommended for children, adolescents, and those at risk. If given at birth, the vaccine can also prevent mother-to-child transmission.

A. Estimate the societal cost resulting from the provisionally notifiable condition [by answering the following:]

A1. Determine the prevalence of the provisional notifiable condition

The CDC[7] estimates that 1.25 million Americans are chronically infected (with 20-30% having acquired the virus in childhood); proportional numbers for Washington State suggest that about 25,000 Washington residents have chronic hepatitis B.

The CDC notes that the rate of new infections has fallen dramatically, from 260,000 per year in the 1980s to 78,000 in 2001. (The proportional figures in Washington State are 5,200 and 1,600, respectively.) They attribute this reduction to routine vaccination of children and adolescents.

Between the start of the provisional notification requirement in December 2000 and July 2003, 1,819 cases of chronic hepatitis B were reported to public health in Washington State. This number, an average of 725 cases per year, represents a minimum estimate because (a) not all infected persons have been tested and (b) even when they have been tested, not all health care providers and facilities have reported all cases to the health department.

A2. Identify the quantifiable costs resulting from the provisionally notifiable condition.

[6] http://www.cdc.gov/ncidod/diseases/hepatitis/b/
[7] http://www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm

The National Alliance of State and Territorial AIDS Directors[8] estimates that the nationwide cost of hepatitis B (in medical expenses and lost wages) is $658 million per year. Proportional costs in Washington State would therefore be approximately $13 million per year.

A3. Determine the qualitative costs resulting from the provisionally notifiable condition

Of those who are chronically infected with hepatitis B, 25% have a chance of developing liver disease which, if caught early, can be treated. Chronic hepatitis B may lead to cirrhosis and liver cancer, which may result in complex treatment and liver transplantation.

B. Describe how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition.

Data can be used to describe populations at high risk for chronic hepatitis B so that targeted programs can be created for vaccination of household contacts and sexual partners. Identifying those with chronic infection can allow for vaccination of household contacts and sexual partners as well as treatment of infants born to mothers who are carriers.

C. Describe the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition.

Vaccination has been shown to be a very effective strategy for reducing the spread of hepatitis B. Additionally, treatment of infants born to mothers who are carriers has also been shown to be highly effective.

D. Identify the quantitative and qualitative costs of the provisional notification requirement.

Cases of chronic hepatitis B are reported by providers and facilities to local health departments, which then report to DOH. Reporting practices vary from county to county. In some counties (probably most), the local health department takes the initiative to gather information from the providers/facilities. Pierce County has had laboratory-based reporting since the early 90s and so does not pursue any provider reporting or fill out case

[8] http://www.nastad.org/PublicPolicyResources/ViralHep.pdf

report forms; DOH is working on electronically transferring their data to our database. (The same is true for Seattle-King County, which also maintains a somewhat separate reporting system.) Although there is a standard reporting form, counties are filling out all different types of forms; DOH also receives some laboratory reports.

Based on an average of 8 minutes to fully process incoming case reports at the state level (receipt, data entry, disposal), it is estimated that approximately 100 hours of staff time are involved in meeting the provisional reporting requirement at an approximate cost of $2,000 per annum. A conservative estimated time burden of completing case reports at the provider level is 5 minutes per case report for a statewide burden of 60 hours per year. Estimating the economic cost of this burden is problematic, but a ballpark figure (using costs of $40 per hour) is $2,400. Most local health jurisdictions bundle provider reports for mailing to the state and have negligible costs associated with meeting the reporting burden.

E. Compare the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement.

A cost comparison is difficult because no data are available on the estimated number of infections prevented due to programmatic interventions.

F. Describe the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data.

Making chronic hepatitis B a notifiable condition was a necessary step to gather information about this disease from across the state. Reporting of this condition is consistent with reporting of other infectious disease conditions, although the number of infections is greater than those reported for many other notifiable conditions. Due to the number of cases of disease reported and the resource burden on some counties, data received on case reports were not always complete, so it is difficult to fully describe the characteristics of those with disease (for example, risk factors or race/ethnicity).

G. Determine whether or not a less burdensome data collection system would provide the information needed to effectively establish and maintain the intervention strategies.

At this time, chronic hepatitis B is reportable by providers and health care facilities but it is not reportable by laboratories. Since case reports are often initiated by positive laboratory results, it may be useful to explore the possibility of making this a condition

reportable by laboratories. This may add to the burden of laboratories, but as electronic systems of reporting get established, this may have less impact.

Lab reporting would not remove the burden from health departments: resources would still be needed so that health department staff could collect information about cases that is not usually reported by labs, such as race/ethnicity and exposure risk. However, lab reporting would probably contribute to more complete reporting of disease.

Hepatitis C – Initial diagnosis and previously unreported prevalent cases

Hepatitis C is a virus (HCV) that often leads to liver disease. The virus is found in the blood of persons who have this disease and is spread by contact with the blood of an infected person. The virus can also be transmitted from an infected mother to her child during birth. There is an important distinction between initial infection with HCV (called *acute* hepatitis C) and ongoing HCV infection (called *chronic* hepatitis C), both of which are provisionally notifiable.

Acute hepatitis C leads to few complications or deaths, and in fact most cases go unnoticed. Approximately 15% of those infected with acute hepatitis C fight off the virus without liver damage or other harm. The remaining 85% develop chronic hepatitis C; complications generally appear after 20 to 30 years of infection.

The most common complication associated with chronic hepatitis C infection is cirrhosis (scarring and loss of function) of the liver, which occurs in 70% of people who have chronic hepatitis C. This potentially deadly infection is the most common reason for liver transplantation in adults in the U.S. In addition, current treatment for chronic hepatitis is expensive, associated with serious side effects, and only effective in 30-70% of those treated, depending on the type of hepatitis C virus causing the infection.

A. Estimate the societal cost resulting from the provisionally notifiable condition [by answering the following:]

A1. Determine the prevalence of the provisional notifiable condition

In Washington State, an estimated 100,000 people are infected with hepatitis C. Of these, approximately 70,000 have developed or will develop chronic infection. As of July 2003, 10,823 cases of chronic HCV were reported to public health in Washington State. (Because acute hepatitis C causes few or mild symptoms, it is probably under-diagnosed and under-reported: only 47 cases of acute hepatitis C were reported in Washington in 2002). This number represents a minimum estimate because (a) not all infected persons have been tested and (b) even when they have been tested, not all health care providers and facilities have reported all cases to the health department.

The CDC[9] notes that the number of new infections nationwide has fallen from about 240,000 per year in the 1980s to 25,000 in 2001. (The proportional figures for Washington State are 4,800 and 500, respectively.) This drop is attributed to blood donor screening (which essentially prevents transmission during blood transfusions) and perhaps to less or safer use of needles by drug users. (Sharing needles is the most common method of transmission.)

[9] http://www.cdc.gov/ncidod/diseases/hepatitis/c/fact.htm

Rates of HCV infection are higher in some groups, including long-term recipients of blood products, patients on dialysis, and injecting drug users.

A2. Identify the quantifiable costs resulting from the provisionally notifiable condition.

The National Institutes of Health[10] estimate the national cost of HCV at $1.2 billion per year. A proportional figure for Washington State would be $24 million. This figure is likely to rise in the coming decade: a recent study[11] predicted a four-fold rise between 1990-2015 in persons at risk for chronic liver disease from hepatitis C virus infection.

A3. Determine the qualitative costs resulting from the provisionally notifiable condition

Of those Washington State residents who are chronically infected with HCV, approximately 15,000 may develop cirrhosis within 20 years and as many as 1,000 may develop liver cancer within 20 years. About 250 deaths occur each year as a result of hepatitis C infection. Hepatitis C is the most common reason for liver transplant.

There is no vaccine to prevent hepatitis C infection. Treatment for infection only works in about 10-40% of persons, depending on a variety of factors. Treatment is costly and can involve significant side effects.

In addition, a recent study[12] concludes that chronic hepatitis C virus infection has a detrimental impact on quality of life and contributes to a reduction in the U.S. workforce.

B. Describe how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition.

Reports from providers to local health jurisdictions on cases of acute hepatitis C allowed the health jurisdictions to investigate the reports of new infection, identify the source of infection, and provide the patient with prevention education. In addition, reporting of chronic hepatitis C provides data to evaluate the magnitude of infection in Washington and to better target prevention efforts at specific at-risk populations. Data collected about

[10] http://www.nida.nih.gov/EconomicCosts/Chapter4c.html
[11] Kim WR. The burden of hepatitis C in the United States. *Hepatology.* 2002 Nov;36 (5 Suppl 1):S30-4.
[12] Jacobs P, et al. Labour force participation among individuals with hepatitis C in the US. *Pharmacoeconomics.* 2003;21(8):565-72.

this condition were presented to the Washington State Department of Health's Hepatitis C Advisory Committee in 2003 to describe the magnitude of the problem in Washington State as well as describe the characteristics of those with chronic infection. The Advisory Committee incorporated these data into the Washington State Hepatitis C Strategic Plan and included the following recommendation: "Improve the state and local health department surveillance system to increase and enhance knowledge of HCV incidence and prevalence in Washington." Data will continue to be used to describe the magnitude and characteristics of the epidemic in order to target prevention and care activities and estimate what resources are needed for these activities.

C. Describe the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition.

Identification of the virus in 1985 and development of testing strategies to screen blood products in 1990s has had a profound impact on reducing the incidence of transfusion-related hepatitis C. For other risk groups, there is not any substantial information on the effectiveness of previous intervention strategies. (This is in part because there were no prior efforts on the state or national level to collect data on those chronically infected with HCV, and in part because Washington State just developed a strategic plan to deal with chronic hepatitis C.) Reducing incidence and prevalence of disease will depend on conducting interventions that lead to prevention of transmission since there is no vaccine available.

D. Identify the quantitative and qualitative costs of the provisional notification requirement.

Cases of acute and chronic hepatitis C are reported by providers and facilities to local health departments, which then report to DOH. Reporting practices vary from county to county. In some counties (probably most), the local health department takes the initiative to gather information from the providers/facilities. Pierce County has had laboratory-based reporting since the early 90s and so they don't pursue any provider reporting or fill out case reports forms – we're working on electronically transferring their data to our database. Seattle-King County also maintains a somewhat separate reporting system and we're working on electronically transferring their data to our database. Although we have a standard reporting form, counties are filling out all different types of forms and we are receiving some laboratory reports.

Based on an average of 8 minutes to fully process incoming case reports at the state level (receipt, data entry, disposal), it is estimated that approximately 70 hours of staff time are involved in meeting the provisional reporting requirement at an approximate cost of $1,400 per annum. A conservative estimated time burden of completing case reports at the provider level is 5 minutes per case report for a statewide burden of 40 hours per year.

Estimating the economic cost of this burden is problematic, but a ballpark figure (using costs of $40 per hour) is $1,600. Most local health jurisdictions bundle provider reports for mailing to the state and have negligible costs associated with meeting the reporting burden.

E. Compare the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement.

A cost comparison is difficult because no data are available on the estimated number of infections prevented due to programmatic interventions.

F. Describe the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data.

Making chronic hepatitis C a notifiable condition was a necessary step to gather information about this disease from across the state. Reporting of this condition is consistent with reporting of other infectious disease conditions, although the number of infections is greater than those reported for many other notifiable conditions. Due to the number of cases of disease reported and the resource burden on some counties, data received on case reports were not always complete, so it is difficult to fully describe the characteristics of those with disease (for example, risk factors or race/ethnicity).

G. Determine whether or not a less burdensome data collection system would provide the information needed to effectively establish and maintain the intervention strategies.

There are currently no alternative means to collect these data, and following the trends is the most effective way to follow the impact of prevention measures statewide

It is worth noting that hepatitis C is currently reportable by providers and health care facilities but it is not reportable by laboratories. Since case reports are often initiated by positive laboratory results, it may be useful to explore the possibility of making this a condition reportable by laboratories. This may add to the burden of laboratories, but as electronic systems of reporting get established, this may have less impact. Lab reporting would not remove the burden from health departments: resources would still be needed so that health department staff could collect information about cases that is not usually reported by labs, such as race/ethnicity and exposure risk. However, lab reporting would probably contribute to more complete reporting of disease.

Herpes simplex (initial genital infection only)

Herpes is a sexually transmitted disease caused by the herpes simplex viruses: type 1 (HSV -1) and type 2 (HSV-2). Reporting of initial genital and neonatal infections began in 1987 and became provisionally notifiable in 2000-2001.

A. Estimate the societal cost resulting from the provisionally notifiable condition [by answering the following:]

A1. Determine the prevalence of the provisional notifiable condition.

Genital Herpes Initial Infection

Initial genital herpes simplex (HSV) infection reporting captures initial infection or diagnoses for either of the two herpes viruses; prevalent or existing HSV infections are not reportable in Washington State.

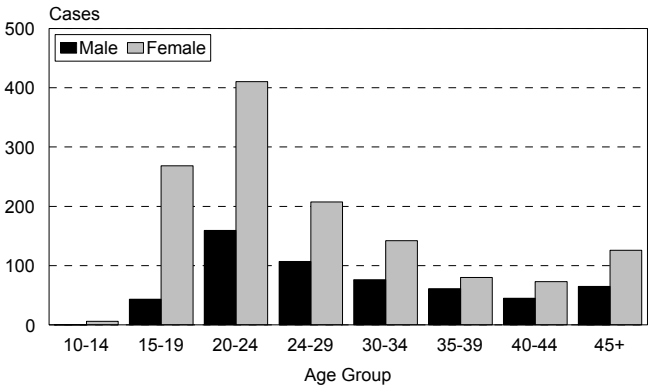
According to the Centers for Disease Control and Prevention (CDC), genital herpes infection is common in the United States. Nationwide, 45 million people ages 12 and older, or one out of five of the total adolescent and adult population, are estimated to be infected with HSV. HSV-2 infection is more common in women (approximately one out of four women) than in men (one out of five). This may be due to male-to-female transmission being more efficient than female-to-male transmission. HSV-2 infection also is more common in blacks (45.9%) than in whites (17.6%). It is estimated that there are more than one million new HSV-1 and HSV-2 infections occurring annually in the United States representing an estimated incidence rate of greater than 341 per 100,000.

Based on reported initial infections in Washington State, the incidence rate of genital herpes has remained relatively stable for the 10 year period from 1993 through 2002 at an average annual reported incidence rate of 34.3 per 100,000 with an average of 1,933 initial infections reported annually. These rates are considerably less than the national annual incidence estimates, which likely reflects both a lower incidence rate than the national rate and significant underreporting. (In turn, national data are also likely to significantly under-represent the true incidence of genital herpes infection because a significant portion of infections are only mildly symptomatic and potentially unrecognized among the infected population.)

In 2002, 430 public and private providers in Washington State reported at least one case of initial infection with genital herpes. Ninety-one percent of these providers reported 10 or fewer cases yet accounted for 51% of the total reported morbidity demonstrating that herpes infection is broadly distributed among Washington State residents. Figures 1 and 2 (below) characterize reported herpes initial genital infection by gender, race/ethnicity and age group for cases reported in 2002.

Figure 1

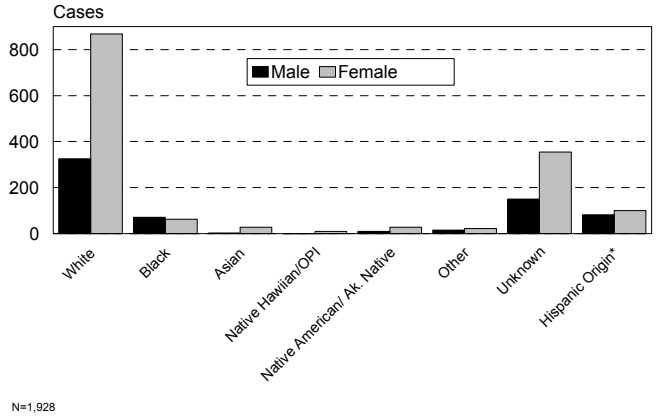
Reported Initial Genital Herpes Infections
by Gender and Age Group, Washington State, 2002



N=1,928

Figure 2

Reported Initial Genital Herpes Infections
by Gender, Race and Ethnicity, Washington State, 2002



N=1,928

Neonatal Herpes Infection

Although neonatal herpes infection appears to be infrequent, the severity of neonatal infections warrants continued research and investigation into the epidemiology and preventative measures necessary to monitor and reduce occurrence. Neonatal infection can lead to severe neuro-developmental impairment in a majority of infected babies and may be a leading cause of rising rates of cesarean deliveries in the United States.[13] Accurate diagnosis of neonatal infection is often problematic and estimates of the incidence of infection nationally range from a low of 1 in 5000 (20/100,000) live births to a high of 1 in 800 (125/100,000) live births[14].

In Washington State, population-based estimates of the incidence of neonatal herpes infection are not generally available through any source other than the provisional notification requirement. However, between 1992 and 1996, 65 cases of neonatal infection were identified, through hospital discharge data and through provisional reporting to the STD/TB Services Section, averaging 11 cases per year for that time period. The average annual incidence rate for this period, 16.5 per 100,000 live births, compares favorably with national incidence estimates. In 2002, there were 6 neonatal herpes infections reported to the STD/TB Services Section.

A2.Identify the quantifiable costs resulting from the provisionally notifiable condition.

Genital Herpes Initial Infection and Neonatal Herpes Infection

The Kaiser Family Foundation[15] estimates the national cost of treating adult/adolescent genital herpes at $208 million per year. Proportional costs for Washington State would be $4 million annually. (A similar estimate comes from a recent journal article[16] that estimated the annual medical costs of herpes simplex to be between $280 and $980 million nationwide. Proportionally, an estimate for Washington State would be $5 to $20 million.)

Excluded from the above estimate is the transmission of genital herpes from an infected mother to her newborn during delivery. Neonatal infection can potentially cost hundreds of thousands of dollars in critical neonatal care in each case. Also excluded from this estimate are the costs associated with unnecessary c-sections performed for women who are known to be infected as a measure to prevent neonatal infection. No reliable data are

[13] Armstrong, et al, 2001; Hansfield, 2001
[14] Marques, Strauss, 2000; *ibid*
[15] STDs in America: How Many Cases and At What Cost? 1998, Menlo Park, CA. Kaiser Family Foundation and The American Social Health Association.
[16] Szucs, Thomas D. et al., "The Estimated Economic Burden of Genital Herpes in the United States. An Analysis Using Two Costing Approaches," *BMC Infectious Diseases* 1:5 (2001).

available to quantify these costs associated with genital herpes infection among women of reproductive age or neonatal infection prevention interventions.

A3. Discuss the qualitative costs resulting from the provisionally notifiable condition.

Genital Herpes Initial Infection

Most individuals have no or only minimal signs or symptoms from HSV-1 or HSV-2 infection. When signs do occur, they typically appear as one or more blisters on or around the genitals or rectum. The blisters break, leaving tender ulcers (sores) that may take two to four weeks to heal the first time they occur. Typically, another outbreak can appear weeks or months after the first, but it almost always is less severe and shorter than the first episode. Although the infection can stay in the body indefinitely, the number of outbreaks tends to go down over a period of years.

HSV-1 and HSV-2 can be found in and released from the sores that the virus cause, but they also are released between episodes from skin that does not appear to be broken or to have a sore. A person almost always gets HSV-2 infection during sexual contact with someone who has a genital HSV-2 infection. HSV-1 causes infections of the mouth and lips, so-called "fever blisters." A person can get HSV-1 by coming into contact with the saliva of an infected person. HSV-1 infection of the genitals almost always is caused by oral-genital sexual contact with a person who has the oral HSV-1 infection.

HSV-1 usually produces only mild symptoms or signs or no symptoms at all. However, HSV-2 can cause recurrent painful genital sores in many adults, and HSV-2 infection can be severe in people with suppressed immune systems. Regardless of severity of symptoms, genital herpes frequently causes psychological distress in people who know they are infected. In the United States, HSV-2 may play a major role in the heterosexual spread of HIV, the virus that causes AIDS. Herpes can make people more susceptible to HIV infection, and it can make HIV-infected individuals more infectious.[17]

Neonatal Herpes Infection

Both HSV-1 and HSV-2 can cause potentially fatal infections in infants if the mother is shedding virus, either through active lesions or through the skin, at the time of delivery. It is important that women avoid contracting herpes during pregnancy because a first episode during pregnancy causes a greater risk of transmission to the newborn. If a woman has active genital herpes at delivery, a cesarean section is usually the preferred method of delivery.

[17] National Center for HIV, STD and TB Prevention, Division of Sexually Transmitted Diseases,

B. Describe how the information was used and how it will continue to be used to design and implement intervention strategies aimed at combating the provisionally notifiable condition.

Genital Herpes Initial Infection

Data from genital herpes initial infection reporting have been instrumental in informing materials development and recommendations to providers for the treatment and case management of genital herpes infection.

Data from reporting of initial genital herpes infection in Washington State have also been used to support successful applications for CDC grants: the University of Washington, Harborview STD Clinic received $600,000 in 2001 to investigate demand for type specific HSV serologic testing in STD, adolescent, gay men's and reproductive health clinics and to assess differences in demographics, risk behaviors, and history of STDs among persons who do and do not agree to HSV serologic testing. This research will be used to design and provide improved herpes prevention initiatives in clinical settings.

Data from reported cases have also been important in establishing base-line disease incidence rates and in assessing disparities in burden of disease by significant demographic factors such as race, ethnicity and gender. The presence of genital ulcers increases the risk of transmission or infection with HIV; analyses of STD morbidity, including genital herpes, based on surveillance data have been instrumental in planning on-going HIV prevention interventions as an indicator of on-going risk behavior. The provisional reporting requirement for initial genital herpes infection has increased awareness of the prevalence of HSV-1 and HSV-2 at the local health jurisdiction and provider level and has led to an increased emphasis on testing and treatment for asymptomatic infections. Surveillance data have also provided a valuable research tool for validating disease data from other sources such as clinical databases and surveys.

Finally, maintaining a registry of infected individuals, eventually reflective of a large portion of prevalent infections, positions the STD/TB Services Section to take immediate advantage of potential vaccine interventions for partners of infected individuals. (A major vaccine trial is underway for a promising candidate—GSK vaccine—so it is possible that a vaccine will become available in 5-10 years.) No other surveillance methodology will provide this capacity, essential for immediate public health response should a vaccine become available. The National Coalition of STD Directors (NCSD) has recommended that CDC fund demonstration projects for herpes prevention in pregnant women and among serodiscordant couples (i.e., couples with one HSV-positive person and one HSV-negative person). Reporting of genital herpes initial infection gives Washington State a crucial advantage in potentially participating in new prevention initiatives.

Neonatal Herpes Infection

Neonatal infection surveillance data have been used to actively ensure proper case management and follow-up of infected neonates. STD/TB Services Section field staff investigate all reported cases of neonatal infection and additional information is collected to document case outcomes.

C. Describe the effectiveness of previous intervention strategies at reducing the incidence, morbidity, or mortality of the provisional notifiable condition.

Other than posters for general STD prevention that mention herpes, there were no specific, herpes-targeted prevention programs.

D. Identify the quantitative and qualitative costs of the provisional notification requirement.

Genital Herpes Initial Infection

Based on an average of 8 minutes to fully process incoming case reports at the state level (receipt, data entry, disposal), it is estimated that approximately 250 hours of staff time are involved in meeting the provisional reporting requirement at an approximate cost of $5,000 per annum. Estimated time burden of completing case reports at the provider level is 3-5 minutes per case report for a statewide burden of 100 – 160 hours per year shared over 430 reporting providers from both the private and public health sectors (in 2002). Estimating the economic cost of this burden is problematic in that salary differentials between clerical and clinical staff are vast and no data are available on what percentage of reports are actually prepared by clinicians versus their clerical staff, but a ballpark figure is $5,000. Most local health jurisdictions bundle provider reports for mailing to the state and have negligible costs associated with meeting the reporting burden.

Neonatal Herpes Infection

Costs associated with reporting of neonatal herpes infections are negligible given the small number of cases incident annually (6 in 2002).

E. Compare the costs of the provisional notification requirement with the estimated cost savings resulting from the intervention based on the information provided through the provisional notification requirement.

A cost comparison is difficult because no data are available on the estimated number of infections prevented due to programmatic interventions. Another unknown concerns the potential development of a herpes vaccine in the coming decade; should such a vaccine become available, the benefits of the provisionally notification requirement would increase considerably because of the availability of a registry of infected individuals.

F. Describe the effectiveness and utility of using the notifiable conditions process as a mechanism to collect these data.

Genital Herpes Initial Infection

The notification requirement serves the public health goals of universally raising provider and local health jurisdiction awareness of the need to screen sexually active adolescents and adults, particularly women of reproductive age, for asymptomatic infection. Further, the existence of a registry of confidential data on persons infected may prove invaluable in successfully deploying a mass vaccination program should an HSV-1 or HSV-2 vaccine become available.

Neonatal Herpes Infection

Reporting of neonatal herpes infections allows for public health field staff to follow-up on reported cases to assure adequate perinatal and neonatal care. No other disease surveillance methodology exists to allow for immediate follow-up.

G. Determine whether or not a less burdensome data collection system (example: biennial surveys) would provide the information needed to effectively establish and maintain the intervention strategies.

Genital Herpes Initial Infection

No other method would provide a disease registry for potential use in vaccine look-back interventions. There are other methods (e.g., simply asking providers and labs to report incidence without requiring reporting) that could provide useful data with respect to population-based incidence and the prevalence of herpes diagnosis. However, the willingness of providers and labs to volunteer this information is questionable, and so the reliability and representativeness of the resulting data would be suspect.

Neonatal Herpes Infection

Other data sources (CHARS/BERD) exist for surveillance of neonatal infection. However, these data sources do not identify patients and are available only with a 6-month lag, so they cannot be used for immediate follow-up and case management of infected neonates.